8-31-1998

Armstrong v. Dwyer

Filed August 31, 1998

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 97-5388

WARREN ARMSTRONG and EMILY ARMSTRONG,
Appellants

v.

WILLIAM DWYER, M.D.; ST. JOSEPH'S HOSPITAL AND MEDICAL CENTER; A. CHRISTIANO, M.D., Director of Labs; VICKIE WILLE, Medical Technician; ATILLA ARTURK, M.D., Transfusionist; GARY NALWANY, M.D., Transfusionist; CELIA GOMEZ, R.N., Transfusionist; A. FERNANDEZ, M.D., Transfusionist; JOHN DOE(S), 1 -3 (individuals responsible for hiring Dr. Thrower); DR. THROWER,

THE PEER REVIEW ORGANIZATION OF NEW JERSEY (PRO NJ)

Intervenor-Defendant

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 93-cv-03016)

Argued June 11, 1998

BEFORE: STAPLETON, COWEN, and RENDELL
Circuit Judges

(Filed August 31, 1998)

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OPINION OF THE COURT

COWEN, Circuit Judge.

Plaintiff-appellant Warren Armstrong appeals from the district court's final judgment entered upon the jury's determination that defendant-appellee, William Dwyer, M.D., was not negligent in providing medical services to plaintiff in the course of three surgical operations and did not breach his duty of informed consent. He also appeals from the district court's orders denying his motion for a new trial and affirming the magistrate judge's order denying his motion to compel Dr. Dwyer to produce all peer review documents pertaining to his treatment of plaintiff. Plaintiff-appellant Emily Armstrong, Armstrong's wife, appeals from

the district court's final judgment entered against her on her derivative claim for loss of consortium.1 We will affirm the district court in all respects.

I.

A. Background Facts

On June 20, 1991, plaintiff met with Dr. Eileen Clifford, an internist in practice with plaintiff's then-treating physician, Dr. Richard Oliver.2 Plaintiff complained of recurring abdominal pain, increasing fatigue, and cramping. He also complained of nausea and a decreased appetite. Dr. Clifford's preliminary assessment was that plaintiff had diverticulitis, a disease in which portions of the colon become inflamed. She prescribed a ten-day course of antibiotics and ordered a barium x-ray of plaintiff 's colon. After several days of antibiotic treatment, however, Dr. Oliver referred plaintiff to Dr. Dwyer for a surgical opinion because the radiologist's report suggested the possibility of an abscess in plaintiff's colon.

Plaintiff met with Dr. Dwyer on July 9 and 12, 1991. Dr. Dwyer reviewed plaintiff 's x-ray and determined that plaintiff had marked diverticulitis in several areas in the upper portion of the sigmoid colon and a possible intramural abscess. Based upon this determination, as well as plaintiff 's medical history and the nature of his complaints, Dr. Dwyer recommended that plaintiff undergo surgery. Dr. Dwyer explained to plaintiff that he would remove the infected section of bowel and rejoin the two healthy bowel ends, a procedure known as an anastomosis.

Dr. Dwyer performed the surgery on July 16, 1991. Initially, plaintiff 's condition appeared to improve, and he was discharged from the hospital on July 27, 1991. Three days later, however, Dwyer readmitted plaintiff after

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1. For the sake of clarity, the court's reference to "plaintiff" herein includes only Mr. Armstrong unless otherwise indicated.

2. All evidence and inferences therefrom are taken in the light most favorable to defendant, the verdict winner. See Doe v. Southeastern Pennsylvania Transp. Auth., 72 F.3d 1133, 1135 (3d Cir. 1995) (citation omitted).

plaintiff complained to him about fever and pain. Dr. Dwyer diagnosed plaintiff with peritonitis, an infection in the abdominal cavity, which resulted from a leak in the anastomosis.

Dr. Dwyer performed a second operation on plaintiff on July 31, 1991. Because he found extensive infection and dead tissue in plaintiff 's abdomen during the surgery, he performed a reversible colostomy with an opening or stoma under plaintiff 's left rib cage. Dr. Dwyer left the incision and wound open to heal "by secondary intention" or without horizontal sutures. App. at 114-15. Plaintiff was hospitalized for more than one month.

Plaintiff met several times with Dr. Dwyer during the next few months. Once again, plaintiff 's overall condition appeared to improve, and his colostomy seemed to be functioning well. By November 12, 1991, however, Dr. Dwyer concluded that the stoma was constricting and additional surgery would be necessary.

Dr. Dwyer performed the revisionary procedure on December 2, 1991 on an outpatient basis. On the following day, plaintiff began treatment with Dr. John McConnell, a rectal and colon specialist. Plaintiff never returned to the care of Dr. Dwyer after his revisionary surgery, and he has not undergone any further surgery.

B. Procedural History

Plaintiff filed the instant action on July 14, 1993, asserting medical malpractice and informed consent claims against Dr. Dwyer.3 Plaintiff alleged that Dr. Dwyer provided improper medical care in connection with his hospitalization, surgeries, and surgery after-care.4 As a

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3. Prior to trial, plaintiff settled his claims against all defendants except Dr. Dwyer.

4. Specifically, plaintiff alleges that Dr. Dwyer deviated from accepted standards of medical care in the following eleven situations: (1) by failing to conduct an antibiotic trial prior to his first surgery; (2) by failing to administer perioperative antibiotic and mechanical bowel preparation prior to the first surgery; (3) in the performance of the first surgery; (4) in the post-operative care given to plaintiff during his initial

result of this alleged negligence, plaintiff claimed that he suffered serious physical and psychological injuries and was left with an undesired, irreversible, and poorly functioning colostomy. He also claimed that Dr. Dwyer failed to secure plaintiff's informed consent for the first and second surgical procedures and that he suffered damages as a result of this breach. Plaintiff's wife, Emily Armstrong, filed a loss of consortium claim for losses she allegedly incurred as a result of her husband's alleged injuries.

On October 6, 1994, plaintiff moved for an order "[c]ompelling the defendant William C. Dwyer to produce all documentation that he has received and all responses given to the Peer Review Organization, relating to his treatment of the plaintiff, Warren Armstrong."5 App. at 122-23. Defendant opposed this motion on the grounds that disclosure of this information was prohibited under the Peer Review Improvement Act of 1982 (the Act), Pub. L. No. 97-248, S 143, 96 Stat. 381 (1982) (codified as amended at 42 U.S.C. SS 1320c to 1320c-22 (1994)), and the so-called self-critical analysis privilege. By consent order dated December 2, 1994, the magistrate judge ordered that Peer Review Organization of New Jersey (PRO NJ) be permitted to intervene in this matter for the limited purpose of submitting a brief in response to plaintiff 's motion to compel.

On January 26, 1995, the magistrate judge filed an opinion and order denying plaintiff's motion to compel the

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hospitalization; (5) by prematurely discharging plaintiff from the hospital after the first surgery; (6) by providing inadequate quality of care to plaintiff during the period in between his discharge from the first hospitalization and his admission to the second hospitalization; (7) by failing to perform surgery on plaintiff as soon as reasonably possible upon plaintiff's readmission; (8) in the performance of the second operation; (9) in the performance of the third operation; (10) in the location of the plaintiff's stoma; and (11) in the formation of plaintiff's stoma.

5. Plaintiff became aware that Dr. Dwyer was the subject of a PRO inquiry after Dwyer's colleague, Dr. Richard Oliver, produced in response to plaintiff's subpoena two PRO documents identifying Dr. Dwyer and plaintiff.

production of peer review documents pertaining to Dr. Dwyer. The magistrate judge held that the documents requested were "absolutely immune from discovery" under the Act because "the responses to PRO inquiries, as well as the inquiries themselves[ ] were generated and created by the PRO . . . ." Magistrate Op. at 9. The magistrate further held that "the documents inadvertently produced by Dr. Oliver are also entitled to the statutory protection against disclosure."6 Id. Because the magistrate denied plaintiff's motion based on the Act, the judge did not consider whether the self-critical analysis privilege would prohibit disclosure of these documents. The district court subsequently entered an order affirming the magistrate judge's order in all respects.

Plaintiff's claims were tried before the district court and a jury between February 19, 1997 and March 19, 1997. The jury returned a verdict in favor of Dr. Dwyer on all of his claims. The jury concluded that plaintiff failed to demonstrate that Dr. Dwyer breached his duty of informed consent or that he acted negligently in providing medical care to the plaintiff. The district court entered judgment on the jury's verdict on May 22, 1997.

Plaintiff filed a motion for a new trial. Plaintiff argued, inter alia, that the district court abused its discretion: (1) by denying the jury's request during deliberations for transcripts of depositions; and (2) by submitting to the jury interrogatories that did not require it to make separate determinations regarding each alleged act of medical negligence and each alleged failure by defendant to obtain plaintiff's informed consent prior to performing surgery upon him. The district court denied plaintiff 's motion. This appeal followed.

II.

The district court exercised jurisdiction pursuant to 28

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6. Although the magistrate judge ordered that plaintiff return to Dr. Oliver the two documents that were produced at Dr. Oliver's deposition, and the district court affirmed this aspect of the magistrate's order, plaintiff has not raised this claim on appeal.

U.S.C. S 1332. This court has appellate jurisdiction of the district court's final judgment pursuant to 28 U.S.C. S 1291.

Our standard of review over the district court's decision not to provide transcripts of depositions to the jury during deliberations is under an abuse of discretion standard. See United States v. Bertoli, 40 F.3d 1384, 1400 (3d Cir. 1994). Likewise, we review the court's formulation of jury interrogatories for abuse of discretion. In re Merritt Logan, Inc., 901 F.2d 349, 367 (3d Cir. 1990). Finally, while we generally review the denial of a motion to compel under the abuse of discretion standard, see Berger v. Edgewater Steel Co., 911 F.2d 911, 916 (3d Cir. 1990) (citations omitted), our standard of review is plenary where the decision is based upon the interpretation of a legal precept. Cf. McAlister v. Sentry Ins. Co., 958 F.2d 550, 552-53 (3d Cir. 1992).

III.

A. Jury's Request for Deposition Transcripts

During the jury's deliberations, the jury sent out the following question to the court: "We need a clarification on this issue: Are we entitled to review any or all of the depositions that are in evidence inside the jury room?" App. at 346. After consulting with counsel, the district judge determined that the jury sought transcripts of depositions, rather than transcripts of the deposition testimony read during trial or a readback of such testimony. Consequently, the district judge told the jury that he would not send the depositions into the jury room because they were not admitted into evidence. The court further instructed the jury that they should rely upon their collective recollection of the depositions that were read into evidence during trial and they should send out another question if the court did not satisfactorily answer their question. No further questions were submitted.

Plaintiff contends that the district court abused its discretion "[b]y refusing the jury's request to review transcripts of deposition testimony entered in evidence, or alternatively, to permit readback of such testimony . . . ."

Plaintiff's Br. at 29 (citing United States v. Bertoli, 40 F.3d 1384 (3d Cir. 1994)). Plaintiff argues that, while such a decision is committed to the sound discretion of the district court, a court's discretion is nevertheless circumscribed by two factors: "whether `(1) such requests may slow the trial where the requested testimony is lengthy; (2) [and] when read only a portion of testimony, the jury may give undue weight to that portion.' " Id. (quoting Bertoli, 40 F.3d at 1400). According to plaintiff, the district court abused its discretion because its ruling was not bottomed on either of these concerns.

Plaintiff's argument merits little discussion. As the district court correctly observed, the jury did not ask for written transcripts of testimony or a readback of such testimony. Instead, the jury requested transcripts of the actual depositions. Because the deposition transcripts were never admitted into evidence, however, we cannot conclude that the district court abused its discretion by refusing the jury's request.

B. Jury Interrogatories

Plaintiff next claims that the district court abused its discretion by refusing to accept his proposed jury interrogatories, which would have required the jury to make findings with respect to each of the eleven alleged incidents of medical malpractice and both of the alleged incidents regarding informed consent. The district court rejected this proposal in favor of the following interrogatories:

> Question 1. Warren Armstrong's Negligence/Medical Malpractice Claim
>
> A. Did plaintiff prove by a preponderance of t he evidence that the defendant Dr. William Dwyer was negligent in providing medical services to the plaintiff?
>
> B. Did plaintiff prove by a preponderance of t he evidence that the defendant's negligence was a proximate cause of some injury and consequent damage sustained by the plaintiff?
>
> Question 2. Walter Armstrong's Informed Consent Claim

A. Did plaintiff prove by a preponderance of the evidence that the defendant failed to comply with his disclosure duty?

B. Did plaintiff prove by a preponderance of t he evidence that the defendant's failure to comply with his disclosure duty was a proximate cause of plaintiff's injuries?

App. at 270-71.

In rejecting plaintiff's proposed malpractice interrogatories, the court stated:

> I understand your point, but you're making the jury's job interminably difficult. Obviously the jury sat here for many days, they listened for example to not only your cross-examination of the witnesses produced by defendant, but Dr. McConnell and they heard his testimony in which he opined in which way he thought Dr. Dwyer had been negligent.
>
> I don't recall whether it was one, five, seven or ten. The point is they heard it. In there--in evaluating their case, your case, they will be in a position to determine whether it's one, three, four, five or ten instances in which the plaintiff proved, by the requisite standard of proof, that Dr. Dwyer was negligent.
>
> It seems to me that my charge, and in my considered judgment, adequately gives them an opportunity to consider all of these charges and make a determination, whether individually or in the aggregate, you demonstrated Dr. Dwyer was negligent and that his negligence was a proximate cause of Mr. Armstrong's injuries.
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> So while I understand what you would like to do, it presents problems which, to coin a phrase, is of Mt. Everest proportions in my judgment and I'm not going to do that.

App. at 278-79. The court employed similar reasoning when rejecting plaintiff's proposed informed consent interrogatories.

Plaintiff contends that the district court abused its discretion by "merg[ing] the numerous factual issues in the case into two vague and broad special interrogatories." Plaintiff 's Br. at 33. Specifically, plaintiff asserts that

> the interrogatories put to the jury did not fairly present the material factual questions. Nothing in Question 1A apprised the jury that it was expected to consider eleven separate deviations in the standard of care alleged to have been committed by Dwyer and testified to by plaintiff's expert weeks earlier. In the same way, Question 2A did not indicate that the informed consent inquiry applied to two separate procedures.

Plaintiff's Br. at 34-35. Once again, plaintiff's argument must fail.

As noted above, the formulation of jury interrogatories is entrusted to the discretion of the trial judge. See In re Merritt Logan, Inc., 901 F.2d at 367; McNally v. Nationwide Ins. Co., 815 F.2d 254 (3d Cir. 1987). " `The only limitation [on this discretion] is that the questions asked of the jury be adequate to determine the factual issues essential to the judgment.' " McNally, 815 F.2d at 266 (quoting Kornicki v. Calmar S.S. Co., 460 F.2d 1134, 1139 (3d Cir. 1972)). In the present matter, the interrogatories submitted to the jury clearly satisfy this standard. By asking whether plaintiff adduced sufficient proof that defendant acted negligently in providing medical care to plaintiff and whether defendant breached his duty of informed consent, as well as whether such negligence or breach proximately caused some injury to plaintiff, the court properly asked the jury to determine the factual issues essential to the judgment. The district judge was not obliged to distill these issues with any greater clarity.

C. Peer Review Improvement Act of 1982

Finally, plaintiff argues that the district court erred in two respects by affirming the magistrate judge's order denying plaintiff's motion to compel defendant to produce all documents received by defendant from the PRO concerning his treatment of the plaintiff and his responses thereto. First, plaintiff contends that, while the Act "excepts from discovery documents `produced by' a PRO `in

connection with its deliberations[,]' " Plaintiff's Br. at 42 (quoting 42 U.S.C. S 1320c-9(d)), the documents at issue here do not fall within this limited category because they consist of "discovery from a target physician of inquiries and notices transmitted to him by the PRO and communications sent by the target physician to the PRO in response." Id. Second, plaintiff contends that the redisclosure regulation, 42 C.F.R. S 476.107(g), requires defendant to produce these documents because the PRO "voluntarily shared allegedly `confidential' documents with Dwyer . . . ." Plaintiff's Br. at 49. We will address each argument in turn.

1. Discovery Barred Under The Act

a. Origin and Function of the PRO and PRO NJ

Congress enacted the Medicare program in 1965 to establish a federally funded system of health insurance benefits for the aged and disabled. See Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. SS 1395 to 1395ccc (1994)). In 1982, Congress amended the Medicare statute by enacting the Peer Review Improvement Act of 1982, Pub. L. No. 97-248, S 143, 96 Stat. 381 (1982), which established "a new method of reviewing the quality and appropriateness of the health care provided . . . to Medicare beneficiaries." American Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1041 (D.C. Cir. 1987). The Act requires that the Department of Health and Human Services (HHS) enter into contracts with "peer review organization," or PROs, private organizations of doctors that review, inter alia, whether medical services "were reasonable and medically necessary" and whether "the quality of such services meets professionally recognized standards of health care .. . ." 42 U.S.C. S 1320c-3(a)(1)(A), (B). "In essence, the Act functions as a quality and fiscal check upon the medical services of physicians and institutions which provide health care services under the Medicare and Medicaid programs." Todd v. South Jersey Hosp. Sys., 152 F.R.D. 676, 685 (D.N.J. 1993).

PRO NJ is a PRO incorporated in the State of New Jersey. PRO NJ was successful in obtaining the first contract with

the Health Care Financing Administration (HCFA) of the HHS and has maintained a contract for Medicare Peer Review in the State of New Jersey since 1984 on a continuous basis. Prior to 1984, the predecessor to PRO NJ, The Southern New Jersey Professional Standards Review Organization, and Area VII Physician's Review Organization, Inc., maintained Medicare peer review contracts with HHS.

b. PRO NJ's Quality Review and Sanction Process

PRO NJ has adopted the following procedures to determine whether a quality issue exists with respect to the care of a Medicare beneficiary. At the outset, a nurse employed by the PRO screens a medical record to determine whether a potential or possible quality question might exist. If the nurse determines that such a question exists, the case is referred to a physician-reviewer of the PRO, who then reviews the matter and determines whether there is, in fact, a potential quality issue.

If the physician-reviewer determines that there is a potential quality issue, the PRO prepares a quality inquiry and issues it to the physician in question. The PRO also requests a response from the physician. The physician generally responds in writing to the quality inquiry by submitting to the PRO a response on the same notice form. Following receipt of the response form from the physician in question, the matter is once again reviewed by the physician-reviewer, who then determines whether there is a confirmed quality problem. If there is no quality problem, an acceptance notice is issued and no further action is taken. However, if there is a confirmed quality problem, the PRO may request further action on the part of a physician. Such action may include a referral to the Sanction Committee of the PRO, a standing committee of the PRO, for additional review and a determination as to whether or not a preliminary determination should be made that a sanctionable offense has occurred.7

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7. There are generally two types of sanctionable offenses: a "gross and flagrant violation" and a "substantial violation in a substantial number of cases." The former offense means that "a violation of an obligation has

In the event that the Sanction Committee makes a preliminary determination that a sanctionable offense occurred, a notice is issued to the physician in question, along with an invitation to meet with the PRO of the New Jersey Sanction Committee (in the case of a gross and flagrant violation) or to respond in writing (in the case of a substantial violation). If a meeting is held with the Sanction Committee, a court reporter is in attendance. Also in attendance is the physician in question, the physician's attorney (if desired), the physician's expert witnesses (if any), and members of the Sanction Committee together with supporting staff.

Following the sanction meeting, the Sanction Committee deliberates and reaches a determination as to whether or not the previous preliminary determination should be affirmed, modified, or reversed. In the event that the preliminary determination is affirmed, the physician is given an opportunity to enter into a corrective action plan, assuming that the physician is willing and able to meet his statutory obligations and the matter before the committee is not considered egregious in nature. Communications between the PRO and the physician then follow, at which time the parties will generally agree upon an approved educational plan which is then implemented by the physician.

In cases considered egregious, or in cases where there is an established pattern of care, the PRO may refer the matter to the New Jersey Office of Inspector General. In that case, a sanction report is prepared and issued to the Office of Inspector General, which contains all of the information upon which the Sanction Committee relied in reaching its determination. A copy of the sanction report is provided to the physician in question, who has a right to

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occurred in one or more instances which presents an imminent danger to health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations." 42 C.F.R. S 1004.1. The latter means "a pattern of providing care . . . that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO." Id.

respond to the Office of Inspector General within thirty days of receipt.

At the conclusion of a quality inquiry with PRO NJ, the physician in question will generally have substantial documentation in his or her file. This documentation may include: (1) the initial quality assurance inquiry; (2) the physician's response; (3) additional correspondence regarding the quality issue; (4) a sanction notice, which includes a quality assurance review sheet, a medical director's committee review sheet, and other information upon which the PRO bases its preliminary determination regarding a sanctionable offense; (5) the physician's written response to the sanction notice; (6) various correspondence related to the sanction process; (7) a determination by the Sanction Committee; (8) correspondence regarding the corrective action plan; and (9) a certification of completion of the corrective action plan.

c. Confidentiality of PRO Information

The Act reflects a strong policy of confidentiality with respect to a PRO's quality review and sanction process. The Act requires a PRO to hold all data and information that it acquires in confidence and, subject to only limited exceptions, prohibits a PRO from disclosing such information. See 42 U.S.C. S 1320c-9(a). Congress has even exempted PROs from the requirements of the Freedom of Information Act. See id. In addition, any person who discloses information in violation of the Act's confidentiality provisions is subject to criminal penalties including a fine and imprisonment of not more than six months. See 42 U.S.C. S 1320c-9(c). Finally, to further protect the confidentiality of PRO-related materials, the Act immunizes many documents from subpoena and discovery proceedings:

> No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceeding in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under

> section 1320c-3(a)(1)(B) or 1320c-5(a)(2) of this title shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's findings and conclusions in making the determination.

42 U.S.C. S 1320c-9(d).

Regulations promulgated pursuant to the Act further buttress these confidentiality provisions. The regulations broadly define confidential information as "(1) [i]nformation that explicitly or implicitly identifies an individual patient, practitioner or reviewer[;] (2) [s]anction reports and recommendations[;] (3) [q]uality review studies which identify patients, practitioners or institutions[;] (4) PRO deliberations." 42 C.F.R. S 476.101(b). Furthermore, "PRO information" includes any information "collected, acquired or generated by a PRO in the exercise of its duties and functions . . . ." Id.

The regulations impose specific requirements to ensure the confidentiality of PRO information. For example, a PRO must provide physical security measures to protect PRO information, including measures necessary to secure computer files. See 42 C.F.R. S 476.115(a). The PRO must furnish confidentiality training and instructions to participants in PRO activities, and must designate an individual responsible for maintaining the system of assuring confidentiality. See 42 C.F.R. S 476.115(a) (c). Only persons who have completed a training program and signed a statement indicating that they understand the penalties for unauthorized disclosure are permitted access to confidential information. See 42 C.F.R. S 476.115(d). In addition, the regulations require a PRO to purge files of personal identifiers as soon as such identifiers are no longer necessary, to destroy hard copies of documents that are no longer needed, and to assure that other organizations providing data services to the PRO have established procedures to maintain confidentiality. See 42 C.F.R. S 476.115(e).

Even where the disclosure of information by a PRO is authorized, the regulations establish procedures to protect

confidentiality. A disclosure requires an accompanying notice and statement advising the recipient of the limitations on permissible redisclosure. See 42 C.F.R. S 476.104. With certain enumerated exceptions, the regulations prohibit any person who obtains confidential PRO information from redisclosing it. See 42 C.F.R. S 476.107.

These extensive provisions reflect a clear congressional policy of protecting the confidentiality of information related to PRO proceedings. This policy is consistent with"the underlying purpose of the federal and state peer review statutes, which is to encourage doctors to evaluate their peers honestly, without fear that the proceedings might later be used in a lawsuit." Todd, 152 F.R.D. at 686 (citing Morse v. Gerity, 520 F. Supp. 470, 471 (D. Conn. 1981)). An assurance of confidentiality is essential to facilitate the open communication necessary for a PRO to perform its duties. The Executive Vice President and Chief Executive Officer of the PRO NJ submitted an affidavit stating that without confidentiality, the organization "would have great difficulty functioning and great difficulty obtaining information now volunteered from physicians to whom quality inquiries are advanced." App. at 167. See also General Care Corp. v. Mid-South Foundation for Medical Care, Inc., 778 F. Supp. 405, 417 n.10 (W.D. Tenn. 1991). As the preceding discussion demonstrates, Congress has clearly created a statutory scheme that is highly protective of information related to PRO proceedings.

d. Analysis

As noted above, plaintiff contends that this section does not bar discovery of the documents at issue because these documents were not " `produced by' a PRO `in connection with its deliberations.' " Plaintiff 's Br. at 42 (quoting 42 U.S.C. S 1320c-9(d)). Specifically, plaintiff argues that: (1) correspondence from the PRO cannot be said to be "in connection with [PRO] deliberations" because these documents "do not include minutes and deliberations whose protection from discovery is the heart of critical self-analysis[,]" id. at 43; and (2) documents written by a "target" physician cannot be considered "generated" by the

PRO. Id. at 46. We conclude that plaintiff's reading of the phrase "produced by [the PRO] in connection with its deliberations" is far too narrow.

"In passing the 1982 amendments, Congress painted with a broad brush, leaving HHS to fill in many important details of the workings of peer review." Bowen, 834 F.2d at 1043; see id. at 1043 (observing that Congress provided "skeletal requirements . . . and left much of the specifics . . . to the inventiveness of the HHS, empowering it to promulgate regulations governing PROs in order to implement the peer review program." (citation omitted)). Two relevant details that HHS filled in are the definitions of "PRO deliberations" and "PRO information." The Secretary defines "PRO deliberations" as

> discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgments about, a particular individual or institution can be discerned.

42 C.F.R. S 476.101(b). "PRO information" is defined as "any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions . . . ." Id.

When PRO NJ's quality review and sanction process is viewed in light of these broad definitions, it is clear the quality review inquiry sent by the PRO to Dwyer were generated by the PRO in connection with its deliberations. The physician-reviewer sent this inquiry to Dwyer after determining that there was, in fact, a potential quality issue regarding Dwyer's treatment of plaintiff. Moreover, the physician-reviewer asked Dwyer to respond to the inquiry. Once Dwyer responded to the inquiry, the physician-reviewer had to consider whether to end the inquiry and send an acceptance notice to Dwyer or to refer the matter to the Sanction Committee of the PRO. Regardless of which course was ultimately taken in this particular case, the physician-reviewer had to render a judgement on the quality of care Dwyer provided to plaintiff. He thus engaged

in the deliberative process within the meaning of the Act, and the inquiry sent to Dwyer was certainly "in connection with" such deliberations.

Moreover, while the status of Dr. Dwyer's responses to the PRO inquiry presents a closer question, we conclude that this information was also generated by the PRO in connection with its deliberations. The physician-reviewer specifically requested that Dwyer assist the PRO by responding to its quality review inquiry. See 42 C.F.R. S 476.101(b) (" `PRO review system' means the PRO and those organizations and individuals who . . . assist the PRO[, and includes] . . . Health care institutions and practitioners whose services are reviewed."). Moreover, Dwyer's responses were generated solely as a result of, and during the course of, the PRO's quality review. As the district court aptly noted,

> Documents utilized by the PRO in the course of its quality inquiry--medical records for example--are discoverable for [sic] any source other than the PRO that might have them. However, documents generated or created by the PRO are not discoverable from any source. Thus, the documents generated by the PRO are absolutely privileged but documents which are generated for another purpose, but which the PRO review in the course of investigating the doctor are not.

Dist. Ct. Op. at 6-7 (citing Todd, 152 F.R.D. at 687, 698). Thus, the PRO generated these responses, which were inextricably linked to the PRO review process and allowed the PRO to perform its responsibilities under the Act. Consequently, Dwyer's responses to the PRO inquiry are not subject to subpoena or discovery.

In addition, the fact that plaintiffs sought to compel these documents from Dwyer, rather than the PRO, does not alter this outcome. Congress provided that the documents or information generated by the PRO in the course of its statutory duties is not subject to subpoena or discovery. See 42 U.S.C. S 1320c-9(d). The bar against discovery runs with the documents or information, not with the organization or individuals who happen to possess the documents or information at any given time. But see Todd,

152 F.R.D. at 686 ("This court finds, therefore, that the Peer Review Protect [sic] Act bars production of documents solely as they exist in the possession of the Peer Review Organization."). Indeed, to hold otherwise would necessarily render the statute's mandate of confidentiality a nullity because a subject physician will have most, if not all, of the materials related to the inquiry within his possession. Thus, the absolute prohibition against discovery of these materials is not destroyed simply because the materials, or copies of the materials, are in the hands of the physician who is the subject of the PRO quality review inquiry and part of the PRO review system. Accordingly, plaintiff's argument must fail.8

2. Redisclosure Not Authorized Under 42 C.F.R. S 476.107(g)

Plaintiff argues in the alternative that, even assuming the documents or information at issue are not subject to subpoena or discovery pursuant to 42 U.S.C. S 1320c-9(d), the regulations governing redisclosure of confidential PRO information require the production of the documents at issue. Specifically, plaintiff argues that

> 42 C.F.R. S 476.107(g) provides that redisclosure of PRO documents from a practitioner is permissible once the PRO has, as in this case, revealed its documents to him. This outcome is dictated by the extinction of any rationale for the continuation of alleged confidentiality once divulgence has occurred and by equity and fairness. This outcome is further dictated in this case by the absence of any reasoned basis for granting derivative immunity to physician-authored documents merely on account of their transmittal to the PRO. The district court's recognition of privilege under those

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8. Although plaintiff suggests in his brief that he also sought production of a corrective action plan from defendant, it is not clear from the record whether this claim was made below. However, in light of our conclusions with respect to the PRO inquiry sent to Dwyer, and Dwyer's response thereto, such a document (assuming it even exists) would unquestionably be deemed a document generated by the PRO in connection with its deliberations.

> circumstances constituted reversible error which requires rectification by the Court.

Plaintiff's Br. at 50. Once again, plaintiff's argument must fail.

The redisclosure regulation provides in pertinent part that "[p]ersons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except . . . (g) [i]nformation pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner . . . ." 42 C.F.R. S 476.107(g) (emphasis added). In the present matter, Dr. Dwyer has never authorized disclosure of the documents. Moreover, disclosure of the PRO documents to defendant and his counsel did not effectuate a "waiver" of the bar against discovery of these materials. This is not a common law privilege to which the traditional concept of waiver applies. Congress deemed that documents or information produced by the PRO in connection with a quality review study shall not be subject to subpoena or discovery. Nothing within this statute supports plaintiff 's contention that this discovery bar may be waived.9

IV.

We will affirm the March 22, 1997 judgment of the district court in all respects.

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9. In light of the foregoing conclusions, we also conclude that the district court properly denied plaintiff's motion for a new trial. See Bertoli, 40 F.3d at 1392 (denial of a motion for a new trial is reviewed for abuse of discretion).